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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

JEAN-LOUIS, SAMIRA JM

ART UNIT

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1617

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/559,681	Applicant(s) RASNETSOV ET AL.	
	Examiner SAMIRA JEAN-LOUIS	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

This Office Action is in response to the amendment submitted on 04/07/09. Claims 1-12 are currently pending in the application. Accordingly, claims 1-12 are being examined on the merits herein.

Receipt of the aforementioned amended claims is acknowledged and has been entered.

Applicant's argument with respect to the two rejections of claims 1-10 under 35 U.S.C. § 112, second paragraph has been fully considered. Given that applicant has amended the claims, such rejections are now moot. Consequently, the rejections of claim 1-10 under 35 U.S.C. § 112, second paragraph are hereby withdrawn.

Applicant's arguments that Gan et al. do not teach a compound of with an anion wherein m is at least 3 have been fully considered. The examiner however points out that applicant is arguing features not previously presented. It is noted that the features upon which applicant relies (i.e., m is at least 3) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). However, in view of applicant's amendment the

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rejection is now moot. Consequently, the rejection of claim 1 under 35 U.S.C. § 102(b) is hereby withdrawn.

Applicant's arguments that Gan et al. teach compounds that are distinct from the amended claims have been fully considered. Applicant further argues that Gan does not provide any suggestion that the fullerene compounds possess any potential pharmaceutical relevance. Additionally, applicant argues that the mere fact that certain fullerene derivatives can be formulated into pharmaceutical compositions does not lead one of ordinary skill in the art to formulate other fullerene derivatives that might be potentially toxic. Such arguments are not persuasive as applicant is arguing features not previously presented. Previously applicant recited an anion component where m was preferably between 3 and 5 thereby suggesting that m of any integer was not precluded. Furthermore, in light of the disclosure of Chiang who teaches that fullerene derivatives can be formulated as pharmaceutical compositions, one of ordinary skill in the art would have indeed found it obvious to try and formulate such compositions. It would have been well within the purview of the skilled artisan to test such compounds for any adverse effects during routine experimentation before formulating such compounds as medicaments. Thus, the Examiner contends that Gan in view of Chiang did indeed render obvious applicant's invention. However, given that the Examiner erroneously rejected claims 4-5 (i.e. instead of claims 3-4) in the last Non-Final Office action mailed on 01/07/09, the Examiner is withdrawing such rejection. Thus, the rejection of claims 4-5 under 35 U.S.C. § 103 (a) is hereby withdrawn.

For the foregoing reasons, the rejections of record are hereby withdrawn. In view of applicant's amendment, the following 112, first paragraph and modified 103 (a) Non-Final rejections are being made.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 3-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As stated by the court in Univ. of Rochester v. G.D. Searle, 69 USPQ2d 1886, 1892 (CAFC 2004), regarding the written description requirement:

The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. A description of an anti-inflammatory steroid, i.e., a steroid (a generic structural term) described even in terms of its functioning of lessening inflammation of tissues fails to distinguish any steroid from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice.... The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described.

In this instant application, applicant did not specifically describe a polycarboxylic anion acid salt wherein m is an integer of at least 3 (see claim 1, line 8). While applicant does disclose in the specification that m is preferably 3 and 5 (see

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specification pg. 6, lines 9 and 25, nowhere in the specification did applicant disclose any ranges or any integers above 3 other than 5. Consequently, due to this lack of written description, the exact interpretation of "at least 3" being claimed by applicant cannot be fully ascertained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-4, and 11-12 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Gan et al. (Chinese Chemical Letters, 1994, Vol. 5, No. 4, pgs. 275-278, previously cited) in view of Chiang et al. (U.S.5,648,523, previously cited).

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Gan et al. teach water-soluble fullerene derivatives that are air-stable (see abstract and pg. 277, last paragraph). In particular, Gan et al. teach that β -alanine sodium salt reacts with C_{60} to give a water-soluble derivative A: $C_{60}(NHCH_2CH_2COO^- Na^+)_x(H)_x$ (i.e. a polycarboxylic anion where m is equal to 2; see pg. 276, top paragraph). Importantly, Gan et al. teach that elemental analysis reveals that x is equal to 9 (i.e. N is 9) and this necessarily reads on the claim limitation where n is an integer from 2 to 12 (see pg. 275, abstract and pg. 276, paragraph 2).

Gan et al. do not teach fullerene derivatives where m is at least 3. Similarly, Gan et al. do not teach the fullerene derivatives in pharmaceutical compositions or formulated as tablets or injections.

The Examiner however contends that it is well within the purview of the skilled artisan to extend the alkyl chain by one carbon as extension by one carbon is expected to result in compounds with similar properties absent of unexpected results (instant claims 1 and 11-12).

Chiang et al. teach fullerene derivatives as free-radical scavengers (see abstract). Importantly, Chiang et al. teach that the fullerene derivatives can be prepared as pharmaceutical formulations which contain an excipient (see col. 5, lines 5-7 and col.

6, lines 26-29). In particular, Chiang et al. teach that the active ingredients can be associated with a carrier which constitutes one or more accessory ingredients (see col. 6, lines 39-43). Chiang et al. further teach that the formulations can be made as tablets or powders wherein the active ingredients are blended with finely divided solid carriers which necessarily include fillers (instant claims 3-4; see col. 6, lines 44-47).

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to try the fullerene derivatives of Gan et al. as pharmaceutical compositions and formulate them in the form of tablets and injections given that Chiang et al. teach formulations of fullerene derivatives as pharmaceutical compositions and in the form of tablets. Additionally, one of ordinary skill in the art would have found it obvious to extend the alkyl chain attached to the fullerene compound by 1 carbon since one of ordinary skill in the art would have expected that extension of the alkyl chain by 1 carbon would have led to compounds of similar properties. Moreover, one of ordinary skill in the art would have found it obvious to try and formulate the modified compositions of Gan et al. as suppositories or injections since these types of formulations are well-known formulations in the pharmaceutical art. Thus, given the teachings of Gan and Chiang, one of ordinary skill would have been motivated to formulate the derivatives of Gan as pharmaceutical compositions and in the form of tablets with the reasonable expectation of providing fullerene derivatives that are soluble in water and air-stable.

Claims 2 and 5-6 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Gan et al. (Chinese Chemical Letters, 1994, Vol. 5, No. 4, pgs. 275-278, previously cited) in view of Miller et al. (RU 2196602 C1, cited by applicant and filed on an IDS 1449).

The Gan reference is as discussed above and incorporated by reference herein. However, Gan et al. do not teach the method of inhibiting virus reproductions using the aforementioned fullerene derivatives. Likewise, Gan et al. do not teach a method of preparing fullerene derivatives.

Miller et al. teach compounds prepared by a single-stage synthesis via direct addition of the residues of amino acids or dipeptides to the fullerene core (see pg. 2, lines 1-2). This is done by adding to a solution of fullerene in o-dichlorobenzene aqueous solution of sodium salt or potassium salt of an amino acid especially aminocaproic and aminobutyric, and 18-crown-6 (instant claim 2; see pg. 2, lines 2-5). The reaction mass is stirred for 6-8 hours at 60C (instant claim 2; see pg.2, line 5). Particularly, Miller et al. teach that the compounds of the invention possess the ability to inhibit HIV and CMV simultaneously (see pg. 3, lines 3-5 and claims 2-3). Additionally, Miller et al. teach that the compounds are able to block the synthesis of structural protein of CMV thereby suggesting inhibition of viral reproduction (instant claims 5-6; see pg. 3, lines 7-8).

Moreover, the examiner contends that while Miller et al. are silent to the addition of a solubilizer in the method of preparing the fullerene derivatives, it would have been well within the purview of the skilled artisan to add solubilizing agents to the method of preparing the fullerene derivatives in order to enhance the solubilization of the aforementioned compounds in water.

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to prepare the modified compound of Gan et al. as taught by Miller et al. and further add solubilizing agents such as PEG agents to the composition in order to enhance the water solubility of the compounds. Additionally, one of ordinary skill in the art would have found it obvious to try the modified compounds of Gan et al. for inhibiting HIV and CMV since Miller et al. teach that similar compounds possess such properties and in view of the fact that similar compounds are expected to possess similar characteristics and/or properties. Thus, given the teachings of Gan and Miller, one of ordinary skill would have been motivated to try the compounds of Gan in view of Miller for inhibition of HIV and CMV with the reasonable expectation of providing fullerene derivatives that are soluble in water and compounds that inhibit both HIV and CMV simultaneously.

Conclusion

No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samira Jean-Louis whose telephone number is 571-270-3503. The examiner can normally be reached on 7:30-6 PM EST M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. J. L. /

Examiner, Art Unit 1617

07/05/2009

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617